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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/542,471

07/15/2005

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EXAMINER

JOIKE, MICHELE K

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

09/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/542,471

Applicant(s)

BOUTONNET ET AL.

Examiner

Michele K. Joiike, Ph.D.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/14/05.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

Claims 14-29 are pending and examined.

Oath/Declaration

It is noted that the Declaration is filed in French in accordance with PCT Rule 4.17(iv).

37 CFR 1.69. Foreign language oaths and declarations.

(a) Whenever an individual making an oath or declaration cannot understand English, the oath or declaration must be in a language that such individual can understand and shall state that such individual understands the content of any documents to which the oath or declaration relates.

(b) ****>** Unless the text of any oath or declaration in a language other than English is in a form provided by the Patent and Trademark Office or in accordance with PCT Rule 4.17(iv), it must be accompanied by an English translation together with a statement that the translation is accurate, except that in the case of an oath or declaration filed under § 1.63, the translation may be filed in the Office no later than two months from the date applicant is notified to file the translation.<

37 CFR 1.69 requires that oaths and declarations be in a language which is understood by the individual making the oath or declaration, i.e., a language which the individual comprehends. If the individual comprehends the English language, he or she should preferably use it. If the individual cannot comprehend the English language, any oath or declaration must be in a language which the individual can comprehend. If an individual uses a language other than English for an oath or declaration, the oath or declaration must include a statement that the individual understands the content of any documents to which the oath or declaration relates. If the documents are in a language the individual cannot comprehend, the documents may be explained to him or her so that he or she is able to understand them.

The Office will accept a single non-English language oath or declaration where there are joint inventors, of which only some understand English but all understand the non-English language of the oath or declaration.

MPEP 602.06

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 14, 15 and 17-29 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,610,508.

Applicants claim a gene expression-inducing fusion protein comprising a ribonucleic acid-binding peptide domain, a translation-activating domain, and a domain enabling delocalization to the cytoplasmic membrane. Applicants also claim the nucleic acid sequence encoding the fusion protein, as well as the vector, the recombined cell, the cell line and a nonhuman transgenic organism. A kit is claimed comprising at least one of these cells.

Claim 23 claims a cell expressing a reporter gene and an effector gene, the reporter gene comprising a binding site for a polypeptide and at least one gene of interest, and the effector gene encoding an inducer fusion protein as claimed comprising at least said polypeptide recognized by the binding site. The Examiner is interpreting this language to mean that the cell expresses a reporter gene comprising a polypeptide binding site, a gene of interest, and a fusion protein as detailed above, as opposed to the reporter comprising a binding site for a polypeptide plus a gene of interest. In further limitations, the cell is eukaryotic; the polypeptide is noneukaryotic. The reporter gene is expressed from a bicistronic RNA.

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Claim 28 claims a modulatable permanent external in vitro method for controlling post-transcriptional gene expression induction in a recombined cell or in a nonhuman transgenic tissue comprising a nucleic acid comprising a sequence encoding a fusion protein as described above, or comprising an expression vector comprising the nucleic acid, by modulating the state of post-translational modification of the fusion protein using an appropriate inhibitor of said post-translational modification.

US 6,610,508 (specifically columns 14-18, 21-24, 26, 45 and 46) teaches a fusion protein comprising an eIF4G-like (translation initiation factor) domain and a RNA binding protein domain (column 14, lines 21-27). eIF4G-like proteins recruit ribosomes to the RNA to activate translation (column 14, lines 36-38). The RNA-binding protein can be a bacteriophage MS2 coat protein (column 24, lines 46-56). Bacteriophage coat proteins insert into the cytoplasmic membrane (as evidenced by Kuhn, A., FEMS Micro. Reviews 17: 185-190, 1995, see entire paper). Therefore, the fusion protein has a domain that enables delocalization to the cytoplasmic membrane.

US 6,620,508 also teaches a vector with a nucleic acid sequence encoding the fusion protein (column 16, lines 18-20), in a recombinant cell (column 16, lines 44-46). Additionally, a cell line (column 24, lines 22-25) or nonhuman transgenic animal (column 46, line 26-30) may be used. A kit can comprise a nucleic acid encoding the fusion protein (column 45, lines 5-46).

US 6,620,508 also teaches a cell comprising an RNA molecule that comprises a reporter gene and can be multicistronic (column 26, lines 13-21). The cell is eukaryotic

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(column 24, lines 22-25) and the polypeptide is noneukaryotic (i.e. bacteriophage coat protein). The effector gene as defined by claim 23 is the nucleic acid sequence encoding the fusion protein. Gene of interest is not defined, so a gene encoding a second reporter, such as CAT, can be the gene of interest (column 18, lines 58-60). The reporter gene can have an HBS (heterologous protein-binding site) (column 18, lines 42-65).

As to the limitations in claim 28, US 6,610,508 teaches a method of differentially modifying the fusion protein during or after translation by glycosylation, acetylation, etc.. Additionally, it teaches controlling post-transcriptional gene expression by modulating the state of post-translational modification using a post-translational modification inhibitor, specifically tunicamycin (column 29, lines 21-46). Tunicamycin inhibits glycosylation. Note: The method in claim 28 is drawn to a permanent in vitro method. Webster's Dictionary (Merriam-Webster's Collegiate Dictionary, 10th Ed., p. 865, 1998) defines permanent as "continuing or enduring without fundamental or marked change." The Examiner is using this definition, as Applicant does not define permanent in the specification, nor gives any length of time for how long the method must be enduring. Since US 6,610,508 does not disclose modifying the method, absent evidence to the contrary, there is no fundamental or marked change in the method. Furthermore, since the method is taking a particular amount of time to be completed, it is enduring for while the method is being performed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,610,508 as applied to claims 14, 15 and 17-29 above, and further in view of Yang et al.

Claim 16 teaches the fusion protein wherein the delocalization domain is a farnesylation domain.

US 6,610,508 teaches all of the limitations as described above, including differentially modifying the fusion protein during or after translation by glycosylation, acetylation, etc.. However, it does not teach modification by farnesylation.

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Yang et al (J. Biol. Chem. 275(1): 429-438, 2000, specifically p. 429) teach modifying a fusion protein by farnesylation, wherein the fusion protein has a farnesylation domain (CAAX).

The ordinary skilled artisan, desiring to use a farnesylation domain, would have been motivated to combine the teachings of US 6, 610, 508 teaching a fusion protein comprising an eIF4G-like (translation initiation factor) domain and a bacteriophage coat protein containing an RNA-binding domain and a delocalization domain, with the teachings of Yang et al, teaching a fusion protein with a farnesylation domain because protein farnesylation is critical for maintaining normal cell morphology. It would have been obvious to one of ordinary skill in the art to use a farnesylation domain because Yang et al teach the importance of farnesylation in growth and transformed phenotypes of cancer cells. Given the teachings of the prior art and the level of the ordinary skilled artisan at the time of the applicant's invention, it must be considered, absent evidence to the contrary, that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Allowable Subject Matter

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on M-F, 9:00-6:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nancy T. Vogel/
Primary Examiner, Art Unit 1636

Michele K Joike, Ph.D.
Examiner
Art Unit 1636